

Kilburn & Strode

European Patent Attorneys
Chartered Patent Attorneys
Trade Mark Attorneys

20 Red Lion Street
London WC1R 4PJ
Tel: +44 (0)20-7539 4200
Fax: +44 (0)20-7539 4299
Email: ks@kstrode.co.uk

Ms M Gadsden
Oxford GlycoSciences (UK) Ltd
The Forum
86 Milton Park
Abingdon
Oxfordshire OX14 4RY

Our Ref: P21647WO/PWC/DMM/AJE
Your Ref: P24-WO01

3 August 2001

Dear Ms Gadsden

International (PCT) Patent Application No. PCT/GB00/00908
In the name of Oxford GlycoSciences (UK) Ltd
Subject: Proteins and their use for diagnosis and treatment of breast cancer

I write to report that we have now received the International Preliminary Examination Report for the above application. Please find enclosed a copy of the report.

The Examiner now considers that claims 1 to 12 are both novel and inventive. However, the Examiner has raised a number of clarity objections in section viii. Firstly, he considered that an essential feature of the invention is that the sample is taken from breast luminal epithelial cells, so this should be included in claims 1 to 3. Secondly, the term "protein features", "BF" and "BPI" are considered to be vague and unclear. In addition the Examiner objects to the fact that the terms BF-1 and BPI-1 refer to the same markers. Thirdly the Examiner considers claims 1 to 3 to be unclear as the subject matter is defined in terms of the result to be achieved. In addition, the Examiner considers claim 8 to be unclear as we cannot see how this method can be carried out if comparisons between normal tissue and cancerous tissue are carried out. These claims can be amended to only refer to "BF" or "BPI" as defined in tables 1 to 4.

The Examiner also raises some clarity objections with reference to claims 6, 7 and 9 as they still refer to tables 1 to 4 as opposed to the specific markers. Obviously, this objection can be overcome by amending the claims to only cover the specific markers as listed in current claim 1.

Claims 13 to 15 and 18 to 21 are considered by the Examiner to lack novelty as antibodies to several of the markers have already been disclosed in the prior art. Similarly, kits containing these antibodies have also been disclosed. Claims 22 to 24 are also considered to lack inventive step as

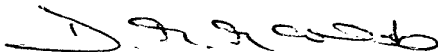
Partners: R.Ashmead N.R.Jennings D.C.Rees M.N.Maggs P.Hale P.W.Chapman J.L.W.Miller
Kristina V.J.Cornish G.V.Roberts T.Z.Gold N.J.Hedley N.C.Bassil N.J.Lee
Associates: T.G.Copsey Julia A.Florence Maureen C.Kinsler Carrollanne H.A.Lindley Punita Shah
Consultants: K.D.N.Kearney A.G.Sheard Alison C.Roberts Elizabeth M.Craichley OBE Ann B.Addison Caroline T.Bonella
Partnership Secretary: B.Collins Records: W.D.D.Green Accounts: B.J.Nutchev

the Examiner considers that it is obvious to a person skilled in the art to treat a patient suffering from breast cancer with antibodies to breast cancer markers.

I take this opportunity to remind you that the deadline for entering the national phase is **12th September 2001**. We would appreciate your instructions regarding this matter as soon as possible, in particular for those countries requiring a translation to avoid incurring any urgency costs.

If you have any questions then please do not hesitate to contact me.

Yours sincerely



Deborah McNab
For Paul W. Chapman
Kilburn & Strode
Encs.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To: CHAPMAN, Paul W. KILBURN & STRODE 20 Red Lion Street London WC1R 4PJ GRANDE BRETAGNE	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; text-align: center;">K+S Received</td> <td style="width: 70%;"></td> </tr> <tr> <td style="text-align: center;">Date</td> <td style="text-align: center;">07 JUN 2001</td> </tr> <tr> <td style="text-align: center;">Entered</td> <td></td> </tr> <tr> <td style="text-align: center;">Checked</td> <td style="text-align: center;">J 18/6</td> </tr> <tr> <td style="text-align: center;">F/E</td> <td></td> </tr> </table>	K+S Received		Date	07 JUN 2001	Entered		Checked	J 18/6	F/E	
K+S Received											
Date	07 JUN 2001										
Entered											
Checked	J 18/6										
F/E											

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Applicant's or agent's file reference PWC/P21647WO		IMPORTANT NOTIFICATION	
International application No. PCT/GB00/00908	International filing date (day/month/year) 13/03/2000	Priority date (day/month/year) 12/03/1999	
Applicant OXFORD GLYCOSCIENCES (UK) LTD. et al.			

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/ <div style="display: flex; align-items: center;"> <div> European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 </div> </div>	Authorized officer Neumann, M Tel. +49 89 2399-7351
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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PWC/P21647WO		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB00/00908	International filing date (day/month/year) 13/03/2000	Priority date (day/month/year) 12/03/1999
International Patent Classification (IPC) or national classification and IPC G01N33/574		
Applicant OXFORD GLYCOSCIENCES (UK) LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 11 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 12/10/2000	Date of completion of this report 05.06.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Jacques, P Telephone No. +49 89 2399 8934



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/00908

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-76 as originally filed

Claims, No.:

1-24 as received on 18/05/2001 with letter of 17/05/2001

Sequence listing part of the description, pages:

1-44, filed with the letter of 24.05.2000

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☒ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets: